

**Amendments to the Drawings:**

The drawing sheet attached in connection with the above-identified application containing FIG. 1a is being presented as a replacement sheet to be substituted for the previously submitted drawing sheet containing FIG. 1a. The drawing FIG. 1a has been amended.

The specific change which has been made to FIG. 1a is that the sensing device has been labeled "16".

**REMARKS**

**Status of Claims:**

Claims 1-27, 29, and 31 remain cancelled. Claims 46-66, 68, and 69 remain withdrawn. New claims 70-78 are added. Thus, claims 28, 30, 32-45, 67, and 70-78 are present for examination.

**Drawings:**

The drawing FIG. 1a has been amended to label the sensing device "16" in accordance with the specification at page 9, line 19. No new matter has been added.

**Claim Rejection Under 35 U.S.C. 112:**

Claims 28, 30, 32-45, and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 28, 30, 32-45, and 67, as amended, the rejection is respectfully traversed.

The Examiner stated that, "[c]laim 28 is unclear in line 3 as to whether the active protein is the active protein in solidified form of line 2". The Examiner suggested that line 3 be amended by inserting "--in solidified form--" after "protein", and that line 5 should be amended before "solidified" by canceling "a" and inserting "--said--".

Claim 28 has been amended in accordance with the Examiner's suggestions. Thus, claim 28, as amended, is believed to be in compliance with the requirements of 35 U.S.C. 112, second paragraph. Because they depend from claim 28, dependent claims 30, 38-45, and 67 are also believed to be in compliance with the requirements of 35 U.S.C. 112, second paragraph.

The Examiner stated that, “[c]laims 32-37 are unclear by not having clear antecedent basis in claim 28 for cross-linking the active protein”, and that, “it is unclear as to the relationship of vapor phase cross-linking in claims 32-37 to the cross-linking reagent of claim 28.” The Examiner posed the following question: “Is vapor phase cross-linking in claims 32-37 using the cross-linking reagent of claim 28, or does vapor phase cross-linking involve cross-linking unrelated to the cross-linking reagent of claim 28?”

Claim 32 has been amended to recite the limitation, “wherein the active protein has been exposed to a vapor phase cross-linking process that **employs said cross-linking reagent** in a vapor phase.” Thus, as recited in amended claim 32, the cross-linking reagent is employed in the vapor phase cross-linking process.

Therefore, independent claim 32, as amended, is believed to be in compliance with the requirements of 35 U.S.C. 112, second paragraph. Because they depend from claim 32, claims 33-34 and 36-37 are also believed to be in compliance with the requirements of 35 U.S.C. 112, second paragraph. Claim 35 has been amended in a similar way as claim 32 has been amended and, thus, claim 35 is believed to be in compliance with the requirements of 35 U.S.C. 112, second paragraph.

The Examiner further stated that, “[c]laims 32-37 are unclear how they further limit the sensor of claim 28”, and that, “[i]t is unclear how the process conditions of these claims change the active protein from that required in claim 28.”

However, the limitations recited in claims 32-37 are, in fact, limitations relating to the sensor as they define a physical state of the active protein (as one that has been exposed to vapor phase cross-linking [claims 32, 35], has been incubated [claim 33, 36], or has been immersed in a cross-linking solution [claim 34, 37]). Since the limitations define a physical state of the active protein, they further limit the sensor of claim 28 and, hence, dependent claims 32-37 are believed to be in compliance with the requirements of 35 U.S.C. 112, second paragraph.

**Claim Rejection Under 35 U.S.C. 102:**

Claims 28, 30, and 32-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Clark Jr. (U.S. Patent Number 6,343,225).

With respect to claims 28, 30, and 32-41, as amended, the rejection is respectfully traversed.

Independent claim 28, as amended, recites a sensor, comprising:

“a sensor body having a space for receiving an active protein in a solidified form; and

the active protein in said solidified form disposed within the space of the sensor body, the active protein in said solidified form comprising glucose oxidase, human serum albumin, and a cross-linking reagent, said active protein having been molded in a recess in a block of a mold and hardened into said solidified form prior to being disposed within the space of the sensor body, said active protein having been received within the space of the sensor body while in said solidified form.” (Emphasis Added).

A sensor including the above-quoted features has at least the advantages that: (i) an active protein in a solidified form is disposed within a space of a sensor body, where the active protein has been molded in a recess in a block of a mold and hardened into the solidified form prior to being disposed within the space of the sensor body; and (ii) the active protein has been received within the space of the sensor body while in the solidified form. By using an active protein that has been molded in a recess in a block of a mold, the active protein may have a proper shape to fit in the space of the sensor body, such as by having a shape that is, for example, semicylindrical, cylindrical, tubular, spherical, and the like. An active protein that is, for example, molded into a desired shape and size before being inserted into a sensor body may reduce a likelihood of swelling or leaching. (Specification; page 6, lines 10-16; page 13, line 1 to page 14, line 3; FIGs. 1a, 3, 4a-4d, 6, and 7).

Clark Jr. neither discloses nor suggests a sensor including the above-quoted features with an active protein in a solidified form that is disposed within a space of a sensor body, where the active protein has been molded in a recess in a block of a mold and hardened into the solidified form prior to being disposed within the space of the sensor body. Instead, Clark Jr. teaches that a mixture is poured onto a glass plate and spread with a glass rod to form a uniform layer of enzyme gel. (Clark Jr.; column 9, lines 35-40). The gel is then used in the device of Clark Jr. by placing a small piece of the gel over a platinum electrode and covering the gel with a membrane. (Clark Jr.; column 9, lines 55-57).

Thus, in the glucose sensor of Clark Jr., the enzyme gel has not been molded in a recess in a block of a mold, but has only been poured onto a glass plate and spread with a glass rod. (Clark Jr.; column 9, lines 35-40). As a consequence, the enzyme gel in the glucose sensor of Clark Jr. is not molded in a recess in a block of a mold into, for example, desired shapes, such as semicylindrical, cylindrical, tubular, spherical, and the like.

Moreover, the gel in the system of Clark Jr. is not in solidified form. The Examiner states that, “[t]he gel of Clark Jr is solidified since it is produced in the form of a self-supporting small piece, and placed over an electrode (col. 9, lines 55-57).” However, while the cited portion of the Clark Jr. reference refers to placing a small piece of gel over a platinum electrode and covering the gel with a piece of cellulose, there is no disclosure or suggestion in Clark Jr. that the gel would be self-supporting. (Clark Jr.; column 9, lines 55-57).

Therefore, independent claim 28, as amended, is neither disclosed nor suggested by the Clark Jr. reference and, hence, is believed to be allowable. Because they depend from independent claim 28, dependent claims 30 and 32-41 are believed to be allowable for at least the same reasons that independent claim 28 is believed to be allowable.

**Claim Rejections Under 35 U.S.C. 103:**

Claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark Jr.

Claims 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark Jr. in view of Blubaugh Jr. et al. (U.S. Patent Number 5,964,993) (hereinafter Blubaugh Jr.).

Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clark Jr. in view of Liston et al. (U.S. Patent Number 4,891,104) (hereinafter Liston).

With respect to claims 42-45 and 67, as amended, the rejections are respectfully traversed.

Claims 42 and 43 depend from independent claim 28. As discussed above, independent claim 28, as amended, is neither disclosed nor suggested by the Clark Jr. reference. Therefore, dependent claims 42 and 43 are believed to be allowable for at least the same reasons that independent claim 28 is believed to be allowable. The Patent Office has not made out a *prima facie* case of obviousness under 35 U.S.C. 103(a).

Claims 44 and 45 depend from independent claim 28. As discussed above, independent claim 28, as amended, is neither disclosed nor suggested by the Clark Jr. reference. Moreover, Blubaugh Jr. does not cure the deficiency with respect to the teaching of Clark Jr. discussed above with regard to independent claim 28. Therefore, dependent claims 44 and 45 are neither disclosed nor suggested by the Clark Jr. and Blubaugh Jr. references and, hence, are believed to be allowable. The Patent Office has not made out a *prima facie* case of obviousness under 35 U.S.C. 103(a).

Claim 67 depends from independent claim 28. As discussed above, independent claim 28, as amended, is neither disclosed nor suggested by the Clark Jr. reference. Moreover, Liston

does not cure the deficiency with respect to the teaching of Clark Jr. discussed above with regard to independent claim 28.

In particular, while Liston discusses a glucose oxidase/bovine serum albumin solution cross-linked with gluteraldehyde which is applied as a bead, Liston neither discloses nor suggests that the bead has been molded in a recess in a block of a mold. (Liston; column 14, lines 38-41). Indeed, Liston does not even care about the exact shape of the bead, because once the bead is applied in the device of Liston, the bead is subsequently compressed to a thin film on a membrane. (Liston; column 14, lines 41-43).

Moreover, the bead in the system of Liston is not in solidified form. In response to applicant's argument that the bead in Liston is a liquid, the Examiner stated that, "this does not appear to be the case since the solution is cross-linked." The Examiner further stated that, "it does not appear a liquid would be capable of being compressed into a thin film", and that, "[i]f the bead in a liquid, it will not be self-supporting, and cannot be transferred to the membrane in bead form."

However, cross-linking does not require solidification. Also, a drop of liquid is readily compressible on a membrane. Liston teaches to compress the bead into a thin film by spreading the liquid across the limiting membrane 600. (Liston; FIG. 14; column 14, lines 38-46). The compression simply refers to squeezing the liquid to form a thin film of the liquid that is spread across the entire limiting membrane 600 (i.e. compressing the vertical dimension of the liquid into a thinner vertical dimension). (Liston; FIG. 14; column 14, lines 38-46). Liquids are very capable of being squeezed to be spread out on a surface when a compression force is applied as in the system of Liston. (Liston; FIG. 14; column 14, lines 38-46). However, a solidified mass would not spread out across a membrane when compressed, but would likely break apart due to the compression force. Thus, Liston teaches away from the bead being in solidified form by teaching that the bead is compressed on the limiting membrane 600 to form a thin film.

Furthermore, Liston does not describe transferring a bead to a membrane. Instead, Liston describes applying a bead of an enzyme to a membrane. (Liston; column 14, lines 38-46). A bead of liquid may be readily “applied” to a membrane by the use of, for example, a dropper (e.g. eye dropper) or the like. Thus, Liston neither discloses nor suggests that the applied bead is in solidified form.

Therefore, dependent claim 67 is neither disclosed nor suggested by the Clark Jr. and Liston references and, hence, is believed to be allowable. The Patent Office has not made out a *prima facie* case of obviousness under 35 U.S.C. 103(a).

**Conclusion:**

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.



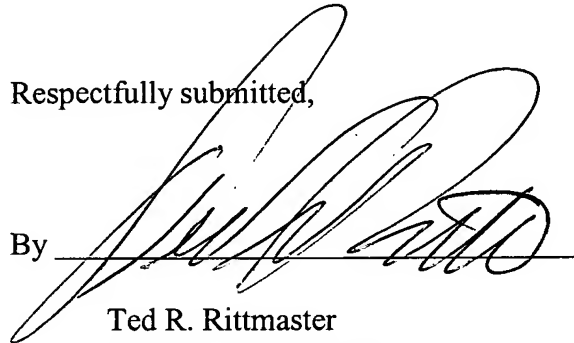
If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

Date

October 3, 2005

By



FOLEY & LARDNER LLP  
Customer Number: 23392  
Telephone: (310) 975-7963  
Facsimile: (310) 557-8475

Ted R. Rittmaster  
Attorney for Applicant  
Registration No. 32,933